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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,196	12/12/2000	John D. Kalvelage	MULTI 9	4254

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EXAMINER

FIDEI, DAVID

ART UNIT

PAPER NUMBER

3728

DATE MAILED: 05/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/734,196

Applicant(s)

KALVELAGE ET AL.

Examiner

David T. Fidei

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-14, 16 and 17 rejected under 35 U.S.C. 102(b) as being anticipate by Allers et al (Patent no. 5,860,549). A sealed blister assembly is disclosed comprising a plastic sheet formed with a recess 25 having an undercut 44. An equivalent lid 12 is attached to cover the opening of the recess. The lid includes a raised ridge 28 adapted to engage the undercut of the plastic sheet.

With respect to claim 3 the ridge 28, i.e., as shown in figure 2a, has walls on both sides leading to the top of arc that flare outwardly. Similarly, the undercut also has “sidewalls” on either side leading to the arc in the bottom of recess 44 to the extent recited in claim 4, see e.g., figure 2B.

As to claims 6-8, conventional materials are contemplated in column 3, lines 14-16 where the subject matter of these claims are believed to be contemplated.

With respect to claims 10, 16 and 17, the undercut sidewalls are shorter than the ridge wall because the ridge walls fist within the undercut and extends beyond and out of the undercut, note figure 4.

As to claim 13 a planar shoulder 42 is formed along the peripheral portion of the sheet used to form the recess 25. A perimeter is also formed around the recess. Also, since the recess of Allers et al is fully capable of receiving medication, this is merely a matter of intended use. A reference that contains all the structure defined in a claim, but not the recited use anticipates the claim because a new use does not make an old product patentable, *In re Schreiber*, 128 F.3d 1473, 44 U.S.P.Q.2d 1429 (Fed. Cir. 1997).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 6-8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allers et al (Patent no. 5,860,549). To the extent that the blister package is not of the class claimed or made of polyethylene, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ polyethylene of Class A or Class B, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

5. Claims 2 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al (Patent no. 6,039,495) in view of Allers et al (Patent no. 5,860,549). Zimmerman discloses a sheet having a plurality of recesses with individual lids sealing the same. The difference between the claimed combination resides in the undercut formed in the perimeter all around the recess. Allers discloses such sealing arrangement in figures 2A. It would have been obvious to one of ordinary skill in the art to modify the sealing arrangement of Zimmerman by constructing an undercut engaging a raised ridge as taught by Allers et al, in order to form a seal in the opening that provides a tighter engagement around the entire periphery.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 11-13, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 13 "the peripheral portion" has no antecedent basis.

In claims 16 and 17 it is not clear what "the dimensions" refers to. Length, width, circumference, peripheral or what parameter this references.

Claims 11 and 12 were discussed in the previous office. These claims define criteria based upon tests. Since prior patents may not have resulted in any commercial devices, it is not possible for the examiner to determine whether meets or exceeds these requirements.

#### ***Response to Arguments***

8. Applicant's arguments filed have been fully considered but they are not persuasive. While it is believed by applicant some unfair conclusions have been drawn by the examiner, careful considered of the claimed subject reveals otherwise.

First, it is well settled mandate that the standard of review during ex parte patent examination is "the broadest reasonable interpretation" standard, see In re Zletz, 13 USPQ2d 1320 (Fed. Cir. 1989), In re Morris, 44 USPQ2d 1023 (Fed. Cir. 1997), In re Hyatt, 54 USPQ2d 1644 (Fed. Cir. 2000). Secondly, it is not seen what is set forth in the claimed subject matter that distinguishes over the prior art as explained above. Unless defined in the claims, it is not where one can imbue subject matter not set forth. In this regard it appears the walls applicant considers as defined by the claims are not the walls referenced in the above rejections.

Applicant recognizes the Allers reference is attempting to seal against gases, vapors and liquids and state "but there is no teaching or suggestion that the seal formed by the structure described in the patent is actually impermeable". Then a patent reference (or the Patent Office) must actually prove it does what it states? The denigration of such a rationale can be easily found in the presumption of validity given each patent which extends to 35 U.S.C. 101 where the reference functions as disclosed.

Allers discloses a ridge described as a protrusion 28 adapted to engage the undercut referred as female nesting recess 44. The equivalent ridge (protrusion 28) comprises walls which

flare outwardly. For example; as shown in figure 2A, the equivalent ridge 28 is formed by two walls which flare outwardly, then circle towards each other to form the top arc of the protrusion 28. Hence the ridge “comprises walls that flare outwardly” as claimed, see claim 3. Similarly, the undercut comprises sidewalls that engage the ridge walls in what is described as a snap-fit where “the ridge and undercut form an impermeable seal, whereby a sealed blister is formed from the plastic lid and the recess of the plastic sheet” (claim 1). Allers makes it plainly clear in column 4, lines 66 to column 5, line 2 that it is this structure which provides “sealing against gases, vapors and liquids”. Hence it is not seen where applicant infers this structure does not perform a seal, nor is it seen where anything in claims 1, 3-14, 15 or 16 distinguishes over the reference.

While there are structural differences between the present invention and the patent to Allers, there is no nexus between these differences and the claimed subject matter. Sidewalls 34 of the base sheet do not appear as engaged with the walls 52 of the lid in the arrangement of Allers. However, the claims refer to walls and sidewalls of the ridge and undercut without any degree of specificity. Accordingly, the subject matter to support applicant’s interpretation is not present in the claims, requires importing limitations or inferences from the specification and is not the broadest reasonable interpretation. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The corresponding structure in the reference to Allers, functioning precisely as claimed, is squarely presented within the four corners of the patent. Thus providing more than a mere scintilla of evidence, but a showing of substantial evidence by the fact finding authority, that applicant has failed to rebut.

With respect to the material, “clear plastic of known type”, applicant states there is no teaching that this plastic has any type of sealing attributes. As noted above, Allers already mentions that the intent of the snap fit is to provide a seal against gases, vapors and liquids. It would seem illogical to provide such a seal and then make the blister from a material that is permeable to the very elements you are trying to guard against. Furthermore, where is it required in the claims that the material have sealing attributes?

While there is no teaching or suggestion in Allers of a plurality of recesses, it is noted the rejection is made under a different statute than anticipation. As such, the combination is evaluated by what the references, taken as a whole suggests, see In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The construction of a plurality of recesses to hold more than one article is fairly taught by Zimmerman et al (Patent no. 6,039,495). The only difference between Zimmerman et al and the claimed subject matter is that the blister include an undercut and ridge rather than the reverse shown in figure 6 of Zimmerman. Allers clearly suggests the engagement structure as a means of attachment for the reason of imparting a sealing function.

With respect to claims 13-15 and 17 applicant avers packaging demands on food is much less than the requirements for medicine. In what way? Even more, what is recited in claim 13 that ties in those more stringent packaging requirements over that of Allers? In so far as the difference between claim 13 and prior patent to Allers, the only distinction involves a matter of intended use. Using a snap-fitting Tupperware ® or Rubbermaid ® type of container to hold medicine rather than food is not as far a field as applicant makes out. Many people put pharmaceutical medication, including aspirin, cold medication, etc., in these container to serve as pill container. Even so, the issue is not that such a use must be shown, but that reference shows all the structure claimed capable of such a use. Which is what Allers clearly does.

#### Claim Rejections - 35 USC § 112

9. As to the rejection under 35 USC 112, second paragraph, applicant submits that incorporation of U.S.P. (which the specification does not disclose what this stands for) test methods are sufficient to explicitly and definitely claim the present invention. If such is the case, the examiner respectfully requests applicant to point out which references of record meet the criteria defining Class A, B or C containers and how applicant arrived at that conclusion. In so far as is gleaned from the specification pages 7 & 8, these tests report vapor transmission rates that the examiner has no way of determining whether or not the prior art meets.

Applicant's insistence on maintaining these claims puts the Patent Office in a position of granting exclusive rights to subject matter that neither the Patent Office or applicant, unless applicant can demonstrate what determines this criteria as requested in the previous paragraph, knows what fulfills such language. This is contrary to the precedent established by examiner's reviewing authority. It has been stated that the second paragraph of 35 U.S.C. 112 requires a claim to particularly point out and distinctly claim the subject matter which applicant regards as his or her invention. Under *In re Hammack*, 166 USPQ 204 (CCPA 1970) and *In re Moore*, 169 USPQ 236 (CCPA 1971), claims must be analyzed to determine their metes and bounds so that it is clear from the claim language what subject matter the claims encompass. This analysis must be performed in light of the applicable prior art and the disclosure. The definiteness of the claims is important to allow others who wish to enter the market place to ascertain the boundaries of protection that are provided by the claims. *Ex parte Kristensen*, 10 USPQ 2d 1701, 1703 (PTO Bd. Pat. App. & Intf. 1989). Accordingly, the rejection in this capacity is believed to be well founded and maintained.

#### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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11. Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c), see MPEP 706.07(a). In considering the remarks and/or amendments to the presently claimed subject matter, the examiner has employed the same art and exact rejections advanced before applicant in the previous office action. This paragraph is included to indicate the examiner thoroughly considered the issues while giving applicant a full and fair hearing, as evidenced by the thoroughness of this action. Neither the statutes nor the Rules of Practice confer any right on applicant to an extended prosecution. Ex parte Hoogendam, 1939 C.D. 3, 499 O.G.3 (MPEP 706.07).

12. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, "should be directed to the group clerical personnel and not to the examiners. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information without contacting the examiners", M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer Service at (703) 306-5648, email [CustomerService3700@uspto.gov](mailto:CustomerService3700@uspto.gov).

Any inquiry concerning the MERITS of this examination from the examiner should be directed to David T. Fidei whose telephone number is (703) 308-1220. The examiner can normally be reached on Monday - Friday 6:30 am - 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached at (703) 308-2672. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 305-8322
Assignment Branch	(703) 308-9287
Certificates of Correction	(703) 305-8309
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If the information desired is not provided above, or has been changed, please do not call the examiner (this is the latest information provided to him) but the general information help line below.

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David T. Fidei  
Primary Examiner  
Art Unit 3728

dtf  
May 24, 2002